K013678

9. SUMMARY STATEMENT OF SAFETY AND EFFECTIVENESS

The VicTorch hCG Test Card device is a lateral flow qualitative color-conjugated immuno-chromatographic (CCI) *in vitro* diagnostic (IVD) assay for human Chorionic Gonadotropin (hCG) at the cutoff level of 20 mIU/ml of human urine, for detection of early pregnancy as commonly used by professionals. Measurements obtained by the qualitative VicTorch hCG Test Cards are used to aid in the diagnosis of pregnancy. VicTorch hCG Test Card devices are classified as Class II Devices, as described in Section 21 CFR 862.1155 Human Chorionic Gonadotropin (hCG) Test Systems, having product code: 91 DHA.

These VicTorch hCG Test Card devices are IVD tests designed to give rapid, visual, qualitative results and are intended for professional use only. VicTorch hCG Test Card devices are not intended for quantitative results, nor for over-the-counter sales. The VicTorch hCG Test Cards provide only preliminary analytical data. A more specific alternative clinical method must be used to obtain a confirmed analytical result.

In order to determine if the VicTorch hCG Test Card devices can function as effectively as other FDA approved and currently marketed similar hCG test devices (such as ABI's SureStep hCG Test Card devices), a number of evaluation studies were done with the VicTorch hCG Test Cards as listed herein. These studies included: (1) Sensitivity studies that includes 20% above and below 20 mIU hCG/ml cutoff concentration and other 0 to 100 mIU hCG/ml levels that indicated the VicTorch hCG Test Card can consistently detect 20 mIU hCG /ml or greater hCG in human urine as it claimed. (2) Specificity studies against other structurally related hormones such as 500 mIU/ml of LH, 1000 μIU/ml of TSH, and 1000 mIU/ml of FSH that shown that these hormones do not cross-react with the VicTorch hCG Test Card at the indicated test levels. (3) Interference studies against analytes commonly found in OTC, prescription and/or abuse drugs proved that those drugs, chemical analytes, and pH (varied within normal range for human urine) did not interfere VicTorch hCG Test Card performance, yielding no false positive or false negative results. (4) The Specimen Collection and Storage Studies on both hCG negative and hCG positive urine specimens validated the VicTorch hCG Test Card devices when tested for urine specimens refrigerated for up to three days. (5) Accuracy studies at an external OBGYN clinical center on 172 female patients (with 91 hCG positive and 81 hCG negative) gave complete agreement (accuracy = 100%) with the ABI's SureStep hCG Test, the predicate approved hCG assay device. (6) In house stability study for both accelerated and real time evaluations showed that the performance of VicTorch hCG Test Card was stable for at least one year from the time of being manufactured. Support data collected from the above evaluation and accuracy studies (i.e., Relative Accuracy = Total # of VicTorch hCG Test Card agreeing with SureStep / vs. Total # of ABI SureStep tested x 100% = 172/172 x 100% = 100%, with at 95% Confidence = 99.1-99.8%) indicate substantial equivalence of this newly designed VicTorch hCG Test Card with the predicate approved hCG assay device.

We can conclude that VicTorch hCG Test Card devices are substantial equivalent to currently marketed ABI's SureStep hCG pregnancy rapid tests devices for professional use qualitative urinary assay of hCG at the required cut-off of 20 mIU/mL. Additional information on this submission may be obtained by contacting: Dr. Pierce Liu, President, at VicTorch Meditek, Inc, via Tel.: (858)-530-9191, Fax: (858)-530-9192, Email: Vtorch99@aol.com.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 7 2001

VicTorch Meditek, Inc.
c/o Raymond Wilson, Pharm. D.
California Department of Health
714/744 P Street
P.O. Box 942732 (MS-357)
Sacramento, CA 94234-7320

Re: k013678
Trade/Device Name: VicTorch Meditek Human Chorionic Gonadotropin (hCG) Urinary Pregnancy Test Card Assay (VicTorch hCG Test Card)
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (hCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: December 12, 2001
Received: December 13, 2001

Dear Dr. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013678

Identity of The Classification: 21 CFR 862.1155; Product Code: DHA

Device Name: VicTorch Meditek Human Chorionic Gonadotropin (hCG) Urinary Pregnancy Test Card Assay (VicTorch hCG Test Card)

INDICATIONS FOR USE STATEMENT:

The VicTorch Meditek Human Chorionic Gonadotropin (hCG) Urinary Pregnancy Test Card device (also known as: **VicTorch hCG Test Card**) is designed as a rapid *in vitro* diagnostic (IVD) qualitative lateral flow color-conjugated immuno-chromatographic (CCI) assay for the early detection of pregnancy, providing a quick direct visual test for the placental hormone, hCG, at the required cut-off level of 20 mIU hCG/ml of human urine. VicTorch hCG Test Card devices are intended to meet all requirements for yielding rapid, easily read, qualitative results for the purpose of early pregnancy detection via CCI assay of hCG, a placental hormone that may be present in human plasma or urine, according to the requirements set forth in Title 21, section 862.1155 of the Code of Federal Regulation or CFR, and in subsequent federal Guidance Documents. VicTorch hCG Test Card devices are not intended for quantitative results, nor for over the counter (OTC) sales. VicTorch hCG Test Card devices are designed for professional use only, and provide only preliminary analytical data. For a final diagnosis of pregnancy, a more specific alternative clinical method must be used to obtain a confirmed analytical result.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ian Cooper
vision Sign-Off)
ision of Clinical Laboratory
K013678

Prescription Use: ✓ **or** **Over-the-Counter Use:** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**